Medical Policy

PARAMOUNT

HMO AND PPO
ELITE (MEDICARE ADVANTAGE)
MARKETPLACE

Gastric Electrical Stimulation (GES)

Policy Number: PG0235
Last Review: 09/01/2024

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.
- Durable Medical Equipment (DME) frequency limitations are calculated based on The Center for Medicare and Medicaid Services (CMS) criteria and guidelines, National Coverage Determinations (NCD), and Local Coverage Determinations (LCD) rules and regulations.

SCOPE:

X Professional
_ Facility

DESCRIPTION:

Gastric electrical stimulation (GES) uses an implanted electrical device with electrodes attached to the stomach to stimulate the coordinated contractions that enable stomach emptying. GES is a treatment for patients who have chronic drug-refractory nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. The device may be referred to as a gastric pacemaker.

Gastroparesis is a chronic disorder of gastric motility characterized by delayed emptying of a solid meal. Symptoms include bloating, distension, nausea, and vomiting. When severe and chronic, gastroparesis can be associated with dehydration, poor nutritional status, and poor glycemic control in diabetics. While most associated with diabetes, gastroparesis is also found in chronic pseudo-obstruction, connective tissue disorders, Parkinson disease, and psychological pathologic conditions. Treatment of gastroparesis includes prokinetic agents such as cisapride and metoclopramide, and antiemetic agents such as metoclopramide, granisetron, or ondansetron. Severe cases may require enteral or total parenteral nutrition.

The only gastric electrical stimulation (GES) device for gastroparesis treatment approved for marketing in the United States is the Enterra™ Therapy System, manufactured by Medtronic, Inc. On March 31, 2000, the FDA approved a Humanitarian Device Exemption (HDE) for the marketing of the Enterra gastric electrical stimulation system for the treatment of chronic, intractable (drug-refractory) nausea and vomiting secondary to paresis of diabetic or idiopathic etiology. Enterra is indicated for the treatment of chronic intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology in patients aged 18 to 70 years. Based upon the FDA label, the Enterra device should not be used for patients with gastric obstruction or pseudo-obstruction, prior gastric resection, fundoplication, eating disorders, history of seizures, primary swallowing disorders, chemical dependency, or psychogenic vomiting.

The first implantable gastric electrical stimulation device to treat obesity is now commercially available in the United States. On January 14, 2015, the Food and Drug Administration (FDA) approved the Maestro Rechargeable (RC) System (Enteromedics) to deliver vagal blocking for obesity control (VBLOC) therapy in

adults who have not achieved adequate results with a supervised weight loss program and who have a body mass index (BMI) ≥ 40 to 45 kilograms per square meter (kg/m2), or a BMI ≥ 35 to 39.9 kg/m2 plus an obesity-related health condition.

POLICY:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

- **Gastric electrical stimulation (e.g., Enterra™ Therapy) (43647, 43648, 43881, 43882) for gastroparesis requires prior authorization for all product lines.**

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Gastric electrical stimulation (GES) may be considered medically necessary when ALL the following criteria are met:

- 18 through 70 years of age; AND
- Chronic, intractable nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology; AND
- Diagnosis confirmed by gastric emptying scintigraphy and/or radiopaque marker testing; AND
- Refractory or intolerant to diet modification and pharmaceutical therapy (e.g., antiemetics, prokinetics); AND
- Significantly poor nutritional status, as evidenced by weight loss of 10% of body weight (for height and age in comparison with pre-illness weight)

Revision or removal of a previously implanted stimulator/pacer meets the definition of medical necessity when used to treat complications associated with gastric stimulation/pacing (e.g., bowel obstruction, gastric wall perforation, infection, lead dislodgement, lead erosion into the small intestine).

Paramount considers gastric electrical stimulation experimental and investigational for all other indications, including but not limited to the treatment of obesity. Refer to PG0237 Vagus Nerve Stimulation (VNS)

CODING/BILLING INFORMATION:

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODES	
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
43882	Revision or removal of gastric neurostimulator electrodes, antrum, open
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
95980	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; intraoperative, with programming
95981	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, without reprogramming
95982	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation,

	cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, with reprogramming
HCPCS CODES	
C1767	Generator, neurostimulator, implantable, non-rechargeable
C1778	Lead, neurostimulator, implantable
C1827	Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller [New Code Effective 01/01/2023]
L8680	Implantable neurostimulator electrode, each
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 06/15/2009

Date	Explanation & Changes
09/09/2014	• Removed CPT codes 0155T, 0156T, 0157T, 0158T deleted 12/31/11 • Policy title changed from Gastric Neurostimulator to Gastric Electrical Stimulation (GES) • Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee
01/23/2015	• Added CPT codes 0313T, 0314T, 0315T, 0316T, & 0317T • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
01/22/2016	• PPO will now be required to do prior authorization for gastric electrical stimulation (e.g., Enterra™ Therapy) for gastroparesis • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
01/27/2017	• Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
01/25/2018	• Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
12/16/2020	• Medical policy placed on the new Paramount Medical Policy Format
02/15/2023	• Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
03/29/2023	• Medical Policy updated to reflect DME limits calculated by CMS criteria/guidelines.
09/01/2023	• Medical Policy reviewed and updated to reflect the most current clinical evidence • Removed deleted codes 0312T, 0313T, 0314T, 0315T, 0316T, and 0317T • Added codes C1827, L8685, L8686 and L8687 • Removed code E0765 and coverage criteria and added it to medical policy PG0244 Electrical Nerve Stimulators, where the coverage relationship applied
03/06/2024	• Medical Policy placed on the new Paramount Medical Policy format
09/01/2024	• Medical Policy reviewed and updated to reflect the most current clinical evidence

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to https://www.paramounthealthcare.com/providers/medical-policies/policy-library

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals
https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs

National Physician Fee Schedule Relative Value File Calendar Year XXXX, Centers for Medicare & Medicaid Services (CMS) https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files

NCCI Policy Manual for Medicare Services, current version, Chapter 1, General Correct Coding Policies https://www.cms.gov/files/document/medicare-ncci-policy-manual-2023-chapter-1.pdf

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

Centers for Medicare & Medicaid Services (CMS), ICD-10-CM Official Guidelines for Coding and Reporting https://www.cms.gov/medicare/coding/icd10

Centers of Medicare & Medicaid Services (CMS), Medicare Claims Processing Manual, Chapter 23-Fee Schedule administration and coding Requirements https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c23.pdf

Centers for Medicare & Medicaid Services (CMS), National Correct Coding Initiative (NCCI) Policy Manual for Medicare Services https://www.cms.gov/medicare-medicaid-coordination/national-correct-coding-initiative-ncci/ncci-medicare

Center for Medicare and Medicaid Services, Medicare NCCI Medically Unlikely Edits (MUEs) https://www.cms.gov/medicare/coding-billing/national-correct-coding-initiative-ncci-edits/medically-unlikely-edits

U.S. Preventive Services Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/
Industry Standard Review

Hayes, Inc., https://www.hayesinc.com/

Industry Standard Review

DESCRIPTION

Gastric electrical stimulation (GES) is performed using an implantable device designed to treat chronic drug-refractory nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. The device may be referred to as a gastric pacemaker.

Gastroparesis is a chronic disorder of gastric motility characterized by delayed emptying of a solid meal. Symptoms include bloating, distension, nausea, and vomiting. When severe and chronic, gastroparesis can be associated with dehydration, poor nutritional status, and poor glycemic control in diabetics. While most associated with diabetes, gastroparesis is also found in chronic pseudo-obstruction, connective tissue disorders, Parkinson disease, and psychological pathologic conditions. Treatment of gastroparesis includes prokinetic agents such as cisapride and metoclopramide, and antiemetic agents such as metoclopramide, granisetron, or ondansetron. Severe cases may require enteral or total parenteral nutrition.

GES is performed using an implantable device designed to treat chronic drug-refractory nausea and vomiting, secondary to gastroparesis of diabetic or idiopathic etiology. One gastric electrical stimulator has received approval from the U.S. Food and Drug Administration (FDA), the Gastric Electrical Stimulator system called Enterra™ Therapy System is manufactured by Medtronic. The data presented to the FDA documenting the "probable benefit" of gastric electrical stimulation (Gastric Electrical Stimulation System) were based on a multi-center double-blind cross-over study (FDA, 2000), which included 33 patients with intractable idiopathic or diabetic gastroparesis. The GES system received FDA approval through a “humanitarian device exemption” (HDE). This regulatory category was established in 1996, and only applies to devices intended to benefit fewer than 4,000 patients.

The first implantable gastric electrical stimulation device to treat obesity is now commercially available in the United States. On January 14, 2015, the Food and Drug Administration (FDA) approved the Maestro Rechargeable (RC) System (Enteromedics) to deliver vagal blocking for obesity control (VBLOC) therapy in adults who have not achieved adequate results with a supervised weight loss program and who have a body mass index (BMI) ≥ 40 to 45 kilograms per square meter (kg/m2), or a BMI ≥ 35 to 39.9 kg/m2 plus an obesity-related health condition.

The ReliefBand is a watch-like device worn on the ventral side of the wrist. When activated, the device emits a low-level electrical current across two small electrodes on its underside, stimulating the median nerve (an acupuncture point). It offers five stimulation levels from the rotary dial that one can control to provide maximum comfort and relief. Studies have shown that the ReliefBand is effective in treating chemotherapy-induced nausea and vomiting and as effective as antiemetic medications in managing nausea and vomiting following surgery. It has also been proven successful in the treatment of hyperemesis gravidarum that is unresponsive to other conservative medical therapy (e.g., change in diet, ginger capsules, vitamin B6).

POLICY

Paramount Commercial Insurance Plans, Medicare Advantage Plans, and Paramount Advantage Medicaid

Gastric electrical stimulation (e.g., Enterra™ Therapy) (43647, 43648, 43881, 43882) for gastroparesis requires prior authorization for all product lines.

Gastric electrical stimulation devices (e.g., Maestro VBLOC Therapy) (0312T-0317T) for the treatment of obesity are non-covered for all product lines.

Transcutaneous electrical acupoint stimulation (E0765) does not require prior authorization for all product lines.

COVERAGE CRITERIA

Paramount Commercial Insurance Plans, Medicare Advantage Plans and Paramount Advantage Medicaid
Paramount utilizes InterQual® criteria sets for medical necessity determinations for gastric electrical stimulation.

Paramount considers gastric electrical stimulation devices experimental and investigational for the treatment of obesity. Refer to PG0237 Vagus Nerve Stimulation (VNS)

Paramount considers transcutaneous electrical acupoint stimulation (prescription version ReliefBand devices) medically necessary for:

- Treatment of post-operative nausea and chemotherapy-induced nausea that is unresponsive to antiemetics and other conservative therapies.
- Treatment of hyperemesis gravidarum that is unresponsive to other conservative medical therapy (e.g., change in diet, ginger capsules, vitamin B6).

Paramount considers transcutaneous electrical acupoint stimulation (prescription version ReliefBand devices) experimental and investigational for the following indications because their effectiveness has not been established:

- Prevention of motion sickness
- Improving pregnancy rates in women undergoing in-vitro fertilization
- Muscle spasticity following brain injury

Note: Paramount does not cover over-the-counter disposable ReliefBand devices, which are used for the treatment of motion sickness, because they do not meet Paramount's definition of durable medical equipment.